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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,699	06/14/2002	Ikuo Nishimoto	082376-000000US	2315

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Joe Liebeschuetz
Townsend & Townsend & Crew
8th Floor
Two Embarcadero Center
San Francisco, CA 94111-3834

EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,699	NISHIMOTO, IKUO	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	waf

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/18/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-21* is/are pending in the application.

4a) Of the above claim(s) *3 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4-8 and 10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the papers filed 4/18/2006. Claims 2-21 are pending. Claims 2, 4-8, and 10-21 are under examination in the instant Office Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/2006 has been entered.

Priority

Acknowledgement is made of Applicant's submission of translations for the foreign patent documents, JAPAN 11-264679 and JAPAN 2000-201456.

Claim Objections

Claim 2 is objected to because of the following informalities: claim 2 recites the phrase "(b) detecting a suppressive effect on the disorder due to the expression of the a nucleic acid of the library" in lines 7-8. It appears Applicant intended "(b) detecting a suppressive effect on the disorder due to the expression of [[the]] a nucleic acid of the library." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites "[t]he method according to claim 2, comprising the step of inducing the cell death associated with said disorder before, during or after step (a), and detecting the suppressive effect on the disorder in step (b) using the suppression of cell death as an index" in lines 1-4. Claim 4 is

vague and indefinite in that there is no proper antecedent basis for "the suppression of cell death." Furthermore, claim 4 is vague and indefinite in that it is unclear what is being measured or assessed by the suppression of cell death "index." Does Applicant intend that the suppression of cell death is an index of whether or not the method of screening for a disorder suppressor gene has been successful, or does Applicant intend that the suppression of cell death is an index of, e.g., how much of a suppressive effect the expression of the nucleic acid has on the disorder, or both?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4-8 and 10-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to methods of screening for a disorder suppressor gene, wherein said method comprises the steps of (a) expressing in a population of cells a library of nucleic acids obtained from or synthesized from nucleic acids expressed in a tissue of an organism suffering from a disorder, wherein said tissue is obtained from an organ showing cell death as a pathological feature of the disorder; (b) detecting a suppressive effect on the disorder due to the expression of a nucleic acid of the library; and (c) selecting the nucleic acid having the suppressive effect; thereby identifying a disorder suppressor gene. Some claims are further drawn to such methods wherein said disorder is a disorder of the cranial nervous system, said disorder is Alzheimer's disease, or wherein said disorder is a neurodegenerative disease. The claims encompass any disorder suppressor gene. The claims encompass the use of any population of cells. The claims encompass any disorder from any organism, as long as the tissue from which the nucleic acids are obtained/synthesized shows cell death as a pathological feature of the disorder. The nucleic acids can be obtained from any part of any organ showing cell death as a pathological feature. The claims encompass any suppressive effect. The claims do not provide any structural information with regard to which disorder suppressor genes can be identified in combination

with the use of which population of cells and which nucleic acids taken from which organs. The claims do not provide any information with regard to which suppressive effects would be selected in which cells with which nucleic acids obtained/synthesized from which organ showing cell death as a pathological feature of the disorder. Thus, the rejected claims comprise a set of methods utilizing cells/nucleic acids/organs that are defined by their function in identifying a nucleic acid "having a suppressive effect."

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes the preparation of a cDNA library from the brain sample of a patient with Alzheimer's disease (AD). The cDNAs were transfected into F11/EcR/V6421I cells, which were then treated with ecdysone for 72 hours, and then plasmids were recovered from the surviving cells (see instant specification at, e.g., page 37, lines 8-36). The specification also describes how sequencing of the clones revealed the sequence for

humanin (HN), which was subcloned into the pFLAG vector to yield pHN (see, e.g., Example 3 on pages 38-39). F11 cells transfected with pHN were protected from the toxic effects of the familial Alzheimer's disease genes V642I APP, NL-APP, M146L PS-1, and N141I PS-2 (ibid and Figure 5). No description of any other working examples utilizing any other cell types/nucleic acids/organs/disorders are provided. No description is provided of how such a method would be performed using DNA from tissue in the area of the organ NOT undergoing cell death.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of one nucleic acid sequence expressed in one cell type and which was obtained from one or synthesized from one organ showing cell death as a pathological feature of the disorder for which a disorder suppressor gene was identified. The results are not necessarily predictive of any other nucleic acid library obtained from any other organ showing cell death as a pathological feature and expressed in any other cell such that a disorder suppressor gene is identified. Thus it is impossible to extrapolate from the example described herein those nucleic acids, disorders, tissues, organs showing cell death, and cells

that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of cells/nucleic acids/organs/suppressive effects that are can be used in such a way as to detect a disorder suppressor gene for any disorder in which an organism suffering from the disorder provides tissue from an organ showing cell death as a pathological feature of the disorder. Saille et al (*Neuroscience* **92**(4):1455-1463, 1999) teach a method for identifying a disorder suppressor gene from brain tissue of mice, but Saille et al do not teach such a method wherein any population of cells, any nucleic acid obtained from or synthesized from nucleic acids expressed in tissue of an organism suffering from a disorder, wherein said tissue is obtained from an organ showing cell death as a pathological feature of the disorder, can be used. Neither does the prior art teach how such a method can be performed with nucleic acids derived from tissue samples not in the area of the organ showing cell death.

Given the very large genus of disorders, cells, and nucleic acids obtained from or synthesized from nucleic acids expressed in a tissue of an organism suffering from a disorder, wherein

said tissue is obtained from an organ showing cell death as a pathological feature of the disorder; and given the limited description provided by the prior art and specification with regard to the chimeric sequences capable of fulfilling the claim limitations of claims 2, 4-8, and 10-21, the skilled artisan would not have been able to describe the broadly claimed genus of cells/nucleic acids/organs that are defined by their function in identifying a nucleic acid "having a suppressive effect." Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those nucleic acid sequences/cells/organs sections that satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded Applicant was not in possession of the claimed invention for claims 2, 4-8 and 10-21.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 2, 4-8, 10-17 and 20-21 under 35 U.S.C. 102(b) as being anticipated by Vito et al (of record) is hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 2, 4-8, and 10-21 under 35 U.S.C. 103(a) as being unpatentable over Vito et al (of record) in view of Slamon et al (of record) is hereby withdrawn.

The declaration under 37 CFR 1.132 filed 4/18/2006 is sufficient to overcome the rejection of claims 2, 4-8, and 10-21 based upon the Vito et al and Slamon et al references as applied under U.S.C 35 §§ 102 and 103. Examiner has considered the arguments and the Matsuoka Declaration, and in view of the preponderance of evidence presented and the probative facts

presented, the rejections made under U.S.C 35 §§ 102 and 103 are hereby withdrawn.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify

applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

June 14, 2006

NANCY VOGEL
PRIMARY EXAMINER